opposite upper and lower surfaces adapted to be placed in contact with and to support the adjacent vertebral bodies, said upper and lower surfaces being non-arcuate;

said opposite sides connecting said upper and lower surfaces and said leading and trailing ends;

an opening passing through said upper and lower surfaces for permitting for the growth of bone from adjacent vertebral body to adjacent vertebral body through said implant; and

said implant being formed by the process of cutting a section of a long bone in a direction transverse to the longitudinal axis of the long bone to form at least a portion of a bone ring and machining said leading end to form said straight portion.

112. (Amended) The implant of claim 111, wherein said lock is made of one of cortical bone and a bioresorbable material.

IN THE DRAWINGS:

Please add new Fig. 11 and amend Figs. 4 and 8 to include the changes marked in red in the Request for Approval of Drawing Changes submitted concurrently herewith.

REMARKS

In the Information Disclosure Statements (IDS) dated June 13, 2000 and February 5, 2002, Applicant submitted an article attributed to Muschler et al. ("The Biology of Spinal Fusion;" Spinal Fusion Science and Technique, Cotler and Cotler, pp.

9-13). The Examiner failed to initial the entry next to Muschler et al. in the IDS dated June 13, and crossed out the Muschler et al. entry in the IDS dated February 5. A copy of the February 5 IDS and PTO Form 1449 with a copy of the Muschler et al. article is attached hereto for the Examiner's convenience. Applicant respectfully requests the Examiner to either consider the reference and initial the entry on the Form 1449 or provide an explanation as to why the Muschler et al. submission is not being considered.

Applicant cancelled claims 130-147 without prejudice or disclaimer of their subject matter and amended claims 1, 43, 85, and 112 to further define Applicant's claimed invention. The amendments to claims 1, 43, and 85 are supported by the language of claims 15, 18, and 57 as originally filed, and Figs. 2A, 2B, and 10.

In the Office Action, the Examiner objected to the drawings under 37 C.F.R. § 1.83(a) for not showing every feature of the invention specified in the claims. Applicant respectfully traverses the objection. 35 U.S.C. § 113 (first sentence) states that "the applicant shall furnish a drawing *where necessary for the understanding of the subject matter to be patented.*" (35 U.S.C. § 113 (first sentence) (emphasis added)). Applicant submits that the subject matter of the claims directed to a lock for locking at least one bone screw, the upper and lower surfaces of the implant having at least a second opening passing therethrough, and the composition of the implant material is subject matter that would be understandable to one of ordinary skill in the art without a drawing.

Further, drawings are not usually considered necessary to understand a recitation of a material or composition, or a combination of a material or composition. MPEP § 601.01(f) states that "...situations in which drawings are usually not considered

necessary for the understanding of the invention under 35 U.S.C. 113 (first sentence) are: (A) Coated articles or products...[and] (B) Articles made from a particular material or composition...." (MPEP § 601.01(f), page 600-14, column 2 (August 2001)).

Nonetheless, in order to expedite prosecution, Applicant amended Fig. 8 with representative shading to show that the implant is made of a composite material. Applicant amended Fig. 4 to include reference number 123 to the lock. Applicant added Fig. 11 to the drawings from Fig. 29 of U.S. Patent No. 6,224,607, which is incorporated by reference in the present application on page 3, lines 1-5 of the specification. Fig. 11 shows an implant having at least two openings in each of the upper and lower surfaces. Applicant amended the specification to include a brief description of Fig. 11. The brief description of Fig. 11 is supported by the brief description of Fig. 29 on page 12 of U.S. Patent No. 6,224,607. No new matter has been added. It is submitted that the objection to the drawings has been overcome.

The Examiner also objected to the specification and suggested that patent application numbers mentioned in the disclosure be updated. Applicant has amended the specification at pages 2, 3, and 8 to substitute the patent numbers for U.S. Patent Application Nos. 08/688,758 and 09/490,901. U.S. Patent Application No. 09/457,228 is still pending. It is submitted that the objection to the specification has been overcome.

The Examiner objected to claims 23, 24, 31, 35, 64, 65, 107, 108, and 112 for various informalities. Applicant amended the specification to provide antecedent basis for claims 23, 24, 35, 64, 65, 107, and 108. No new matter has been added. With respect to the objection of claim 31, Applicant respectfully disagrees with the Examiner's

assertion that the combination of bone and composite material is not supported by the specification other than the original claims. The specification at page 5, lines 8-13 refers to a "bone composite" material comprising bone and any other suitable material. Additional support for claim 31 may be found in the specification on page 10, lines 5-8 and page 12, lines 13 and 14. Applicant amended claim 112 to depend from claim 111 as suggested by the Examiner. It is submitted that the objection to claims 23, 24, 31, 35, 64, 65, 107, 108, and 112 has been overcome.

The Examiner rejected claims 1-22, 25-35, 43-63, 66-77, 85-106, 109-119, and 127-129 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,277,149 to Boyle et al. Applicant amended independent claims 1, 43, and 85 to recite that the trailing end of the implant is at least in part curved along "a middle portion" of the trailing end.

Boyle teaches a cortical ring implant with machined sidewalls and curved edges. (Boyle, col. 3, lines 31 and 32; and Fig. 7). Boyle does not teach an implant having a trailing end that is at least in part curved along a middle portion of the trailing end of the implant as claimed by Applicant. Applicant submits independent claims 1, 43, and 85 are allowable and that dependent claims 2-22, 25-35, 44-63, 66-77, 86-106, 109-119, and 127-129 are allowable at least because they depend directly or indirectly from an allowable independent claim.

The Examiner also rejected claims 36-42, 72, 78-84, and 120-126 under 35 U.S.C. § 103(a) as being unpatentable over Boyle and rejected claims 23, 24, 64, 65, 107, and 108 under 35 U.S.C. § 103(a) as being unpatentable over Boyle in view of U.S. Patent No. 5,669,909 to Zdeblick et al. Applicant submits that the Examiner's

rejections of these claims are rendered moot at least in view of the patentability of amended independent claims 1, 43, and 85, which Applicant submits are in condition for allowance. Applicant further submits that dependent claims 23, 24, 36-42, 64, 65, 72, 78-84, 107, 108, and 120-126 are also allowable at least due to their dependency directly or indirectly from independent claims which are allowable over the cited references.

In view of the foregoing amendments and remarks, Applicant respectfully requests the reconsideration and reexamination of this application and the timely allowance of the pending claims.

To the extent any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this reply, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 50-1066.

Respectfully submitted,

MARTIN & FERRARO, LLP

Dated: December 17, 2002

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BOX AF
RESPONSE UNDER 37 C.F.R. 1.116
EXPEDITED PROCEDURE
EXAMINING GROUP 3738

PATENT
Attorney Docket No. 101.0078-00000
Customer No. 22882
Express Mail No. EV 044 233 542 US

CHANGES TO THE SPECIFICATION

Please amend the specification as follows:

The paragraph bridging pages 2 and 3:

--The present invention is directed to a major long bone ring implant preferably, but not necessarily, an implant formed from a diaphyseal ring for insertion into an implantation space formed across a spinal disc between two adjacent vertebral bodies of the spine. The bone ring implant is preferably used in an implantation space having a wall portion, lip, or ridge with a flat portion for abutting the leading end of the bone ring implant. Such an implantation space can be formed with the instrumentation and method set forth in applicant's U.S. Patent No. 6,159,214~~application serial no. 08/688,758~~, titled "Milling Instrumentation and Method for Preparing a Space Between Adjacent Vertebral Bodies", incorporated by reference herein. It is appreciated however, that the bone ring implant of the present invention can be useful in implantation spaces formed by other techniques, such as for example, applicant's U.S. Patent No. 6,224,607~~application serial no. 09/490,901~~, titled "Instrument And Method For Creating An Intervertebral Space For Receiving An Implant", incorporated by reference herein.--

Page 6, seventh full paragraph:

FIG. 8 is a trailing end view of a bone compositering implant in accordance with a third embodiment of the present invention.

Paragraph bridging pages 7 and 8:

FIG. 1 shows a top plan view of a vertebral body V with an implantation space 20 created therein for receiving an implant. Implantation socket or space 20 has a posterior wall 22 and side walls 24, 26 formed at least in part in the cortical bone endplate of vertebral body V. By way of example and not limitation, implantation space 20 may be created with the apparatus and methods disclosed in applicant's U.S. Patent No. 6,159,214~~application serial no. 08/688,758~~.

Page 11, second full paragraph:

The bone ring implants, bone screws, or locks 123 could include a bioresorbable material including, but not limited to cortical bone, plastics and composite plastics. Suitable plastics may include those comprising lactides, galactides, glycolide, capronlactone, trimethylene carbonate, dioxanone in various polymers and/or combinations. The implant may further include a material, other than the bone from which the implant is formed, that intrinsically participates in the growth of bone from one of the adjacent vertebral bodies to the other of the adjacent vertebral bodies.

Page 12, first full paragraph:

While a preferred embodiment of the present invention has been described in regard to a femoral ring modified in accordance with the teachings of the present invention, the invention itself is not so limited. While a femoral

ring, because of its diameter, lends itself well to use in the human adult lumbar spine, other tubular bones may be useful in various locations of a human spine. By way of example only and not limitation, rings formed through the diaphyseal region of a fibula or humerus may be used for interbody fusion in the cervical spine, while a tibial ring may be used in the thoracic or lumbar spine. Finally, the implants of the present invention may be formed from a composite material comprising cortical bone (Fig. 8).

BOX AF
RESPONSE UNDER 37 C.F.R. 1.116
EXPEDITED PROCEDURE
EXAMINING GROUP 3738

PATENT
Attorney Docket No. 101.0078-00000
Customer No. 22882
Express Mail No. EV 044 233 542 US

CHANGES TO THE CLAIMS

Please amend the claims as follows:

1. (Twice amended) An interbody spinal implant made of cortical bone for insertion at least in part into an implantation space formed across the height of a disc space between adjacent vertebral bodies of a human spine and into at least a portion of the endplates of the vertebral bodies, the implantation space having a front wall, said implant comprising:

a body manufactured from a bone ring obtained from a major long bone of a human, said body having a perimeter, a leading end for insertion first into the disc space, a trailing end opposite said leading end, and opposite sides, said body having a length along a mid-longitudinal axis of said implant, said leading end having a generally straight portion along a portion of the perimeter of said body adapted to abut the front wall of the implantation space when said implant is installed into the implantation space, said trailing end being at least in part curved along a middle portion of ~~the perimeter of~~ said trailing end~~body~~;

opposite upper and lower surfaces adapted to be placed in contact with and to support the adjacent vertebral bodies, said upper and lower surfaces being non-arcuate;

said opposite sides connecting said upper and lower surfaces and said leading and trailing ends; and

an opening passing through said upper and lower surfaces for permitting for the growth of bone from adjacent vertebral body to adjacent vertebral body through said implant.

43. (Twice amended) An interbody spinal implant made of a bone composite material for insertion at least in part into an implantation space formed across the height of a disc space between adjacent vertebral bodies of a human spine and into at least a portion of the endplates of the vertebral bodies, the implantation space having a front wall, said implant comprising:

a body manufactured from a bone composite material, said body having a perimeter, a leading end for insertion first into the disc space, a trailing end opposite said leading end, and opposite sides, said body having a length along a mid-longitudinal axis of said implant, said leading end having a generally straight portion along a portion of the perimeter of said body adapted to abut the front wall of the implantation space when said implant is installed into the implantation space, said trailing end being at least in part curved along a middle portion of ~~the perimeter of~~ said trailing end~~body~~;

opposite upper and lower surfaces adapted to be placed in contact with and to support the adjacent vertebral bodies, said upper and lower surfaces being non-arcuate;

said opposite sides connecting said upper and lower surfaces and said leading and trailing ends; and

an opening passing through said upper and lower surfaces for permitting for the growth of bone from adjacent vertebral body to adjacent vertebral body through said implant.

85. (Twice amended) An interbody spinal implant made of cortical bone for insertion at least in part into an implantation space formed across the height of a disc space between adjacent vertebral bodies of a human spine and into at least a portion of the endplates of the vertebral bodies, the implantation space having a front wall, said implant comprising:

a body manufactured from a bone ring obtained from a major long bone of a human, said body having a perimeter, a leading end for insertion first into the disc space, a trailing end opposite said leading end, and opposite sides therebetween, said body having a length along a mid-longitudinal axis of said implant, said leading end having a generally straight portion along a part of the perimeter of said body adapted to abut the front wall of the implantation space when said implant is installed into the implantation space, said trailing end being at least in part curved along a middle portion of ~~the perimeter of~~ said trailing end~~body~~;

opposite upper and lower surfaces adapted to be placed in contact with and to support the adjacent vertebral bodies, said upper and lower surfaces being non-arcuate;

said opposite sides connecting said upper and lower surfaces and said leading and trailing ends;

an opening passing through said upper and lower surfaces for permitting for the growth of bone from adjacent vertebral body to adjacent vertebral body through said implant; and

said implant being formed by the process of cutting a section of a long bone in a direction transverse to the longitudinal axis of the long bone to form at least a portion of a bone ring and machining said leading end to form said straight portion.

112. (Amended) The implant of claim 111~~110~~, wherein said lock is made of one of cortical bone and a bioresorbable material.